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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,640	03/01/2004	Michael D. West	60141.0022USU2	9766
	7590 04/04/2007 seph Bennett-Paris	EXAMINER		
MERCHANT &	& GOULD P.C.		BERTOGLIO, VALARIE E	
P.O. Box 2903 Minneapolis, M	IN 55402-0903		ART UNIT	PAPER NUMBER
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SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Application No. Application No. 10/790,540 WEST ET AL.			A 12 A2 10				
Examiner Valarie Bertoglio 1632 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address → Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be firmly filled where 3X (s) MONTHS from the mailing date of this communication. - Providence of the providence of a post-date of the communication of the providence of a post-date of the communication. Providence of a post-date of the communication of the providence of a post-date of the communication. Providence of a post-date of the communication of the providence of the providence of the communication. Providence of the providence of the communication of the providence of the providence of the communication of the providence of the pro			Application No.				
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2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:	1) Notice 2) Notice 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P	ate			

DETAILED ACTION

Applicant's election dated 12/14/2006 has been received. Claims were amended to comply with 37 CFR 1.121, the amendment being received 01/29/2007. Claims 69-105 were added.

The instant application is a continuation of USSN 09/527,026, now abandoned.

Election/Restrictions

Applicant's election without traverse of Group II, claims 15,16,24 and 26 in the reply filed on 12/14/2006 is acknowledged.

Upon further consideration of the claims, Groups I and II are rejoined. Newly added claims 69-105 are drawn to products made by the method of Group I. Claims 1-105 are pending and claims 40-67 are withdrawn as being drawn to a non elected invention. Thus, claims 1-39, and 68-105 are under consideration in the instant office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: The specification contains several references to a URL (for example: page 6, line 7; page 8, line 20). The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable

code is considered to be an improper incorporation by reference (See MPEP 608.01(p)). Appropriate correction is required.

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It is also noted that the first line of the specification should be updated to reflect the status of parent application 09/527,026 as abandoned (see page 2 of the Request for Filing a Continuation dated 03/01/2004).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 11/079,930. This is a <u>provisional</u> double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,808,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims in the '704 patent are of a broader scope than the instant pending claims. Further allowed claims 1 and 4-6 recite the steps of pending claim 1, and with regard to a primary cell, claim 6 is drawn to isolating a fibroblast which is a primary cell.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-39, and 68-105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of providing primary cells comprising: a) enucleating an oocyte of a first mammalian species and transferring the nucleus of the primary cell from the same species as the oocyte into said oocyte; b) activating the NT unit; c) culturing the activated NT unit in a immunocompromised mammal to produce a teratoma; and d) isolating a differentiated cell from said teratoma and said differentiated cells isolated from said teratoma, does not reasonably provide enablement for use of any source of host cell from a first species, nor the use of any organism besides a mammalian species, nor use of a non-enucleated oocyte. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPO2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

The basis of the rejection is not directed towards the intended use of said cells, rather to the nature and breadth of claimed invention. The recitation of cells for transplantation (e.g. claim 13) is not being interpreted as an intended use but rather as a characteristic of the cells.

The claims are drawn to a method of nuclear transfer wherein the resulting differentiated cell represents a rejuvenated primary cell. The claims are broad drawn to any organism, including animals and plants. The specification teaches, by reference to Wilmut at al, 1997, the production of cells by use of nuclear transfer into an enucleated oocyte, and relies in great part on specific teachings in the prior art to practice the claimed process. The claims fail to require that the recipient oocyte be enucleated and do not require an enucleation step.

The specification provides examples for the production of a cell using nuclear transfer methodology. CL53 bovine fetal fibroblast cells were passaged until 95% of their lifespan was completed. The CL53 cells were used to reconstitute bovine oocytes (page 30) and grown to result in a liveborn calf. Measurement of proliferative life of cells from a cloned fetus and the original donor fetus were compared and demonstrated that the proliferative life of the clone is reset (page 32). Telomere length was also demonstrated to be restored (page 33). The specification teaches that the resulting cell has increased telomere and telomerase activity.

With respect to the breadth of the claims encompassing use of any organism as either nuclear donor and cell source recipient (plant, human, yeast, etc), the nature of the invention requires that the donor nucleus be 'reprogrammed' such that totipotency or pluripotency is achieved. At the time of filing the art required that the donor nucleus be in contact with the cytoplasm of an oocyte. Kono teaches that a break down of the nuclear envelope is necessary for reprogramming, as reprogramming probably requires the contact of chromatin with the ooplasm (**Rev Reprod.** 1997 May;2(2):74-80, specifically page 76, second column, lines 1-6). Further, it is recognized that the oocyte would need to be enucleated so that the developing embryo would retain the correct ploidy.

The claims encompass a method of nuclear transfer wherein the resulting cell derived from an embryo is a rejuvenated primary cell. The basis of this aspect of the rejection is directed towards the breadth encompassed by the specific method step of using a nuclear donor and an oocyte from two different and unrelated species. The art supports that the donor nucleus is reprogrammed by yet unknown components of the recipient cytoplasm where the donor nucleus is reverted to the same morphological and temporal pattern of the zygote. Further, the art indicates that while the nucleus of one species can be physically transferred into the oocyte of second different species, the resulting chimeric embryo is incapable of supporting the proliferation of said embryo. Depending on the phylogenetic distance of the

two species used in the nuclear transfer method, after several rounds of division the cells in the chimeric embryo cease to proliferate, thus cross-species nuclear transfer can not result in a rejuvenated cell.

Because the instant application relies heavily on the teachings of the art to carry out the claimed invention, the Examiner would agree that the examples recited in the instant specification are enabled by the methodology commonly practiced in the art, however the claims are not limited to these enabled embodiments. The only enabled recipient cell in the art is an enucleated mammalian oocyte, and the instant specification fails to provide a nexus for use of any other type of recipient cell or in any other organism beside a mammal. In light of Applicant's reliance on the art for practice of the claimed process and resulting cell, the instant specification and the art of record fails to provide the necessary guidance which would enable the artisan to practice the invention commensurate in scope as instantly claimed.

Additionally, claims 25-39 are drawn to propagating the cell in a target species and into an animal. In light of the teaching of the instant specification, the implantation and propagation is intended to be into a pseudopregnant female host wherein the host is the same species as the donor nuclei, however, the claims embody transfer into any organism. With regard to the specific teachings in the specification, the art would fully enable the transfer of a NT unit comprising an enucleated oocyte from a first mammal and the nucleus/mitochondria from a second mammal into a pseudopregnant female of the same species of the second mammal. However, there is no teaching in the specification nor the art of record which demonstrates the necessary guidance needed to transplant a developing embryo into a species with a different genetic background (i.e mouse nuclei/mitochondria into a host cow). The claims encompass introducing an ES cell into a recipient female and allowing the ES cell to develop into a newborn animal. However, it is well known in the art that an ES cell, by itself, does not give rise to an animal but can contribute to all cell lineages of an animal when transferred into a developing blastocyst. Further, the full breadth of the claims encompass the transplantation into any area of the targeted species, in any species. It Application/Control Number: 10/790,640

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is well recognized in the art that transplantation of cells across various species, i.e. xenotransplantation,

has not been successfully performed except into immunocompromised animals.

In view of the lack of guidance in the instant specification to perform these processes, and in light

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of the art recognized limitations of xenotransplantation, it would require undue experimentation for the

artisan to practice the full scope of the invention as claimed. In the detailed description of the invention, it

is stated that the invention provides a method for rejuvenating primary cells through nuclear transfer

techniques (page 1; first lines). The invention, in great part, relies on Applicant's observation that

practicing nuclear transfer methods, that a donor cell nucleus can be reprogrammed to become a

pluripotent cell when transferred into an oocyte and properly cultured. However, the specification fails to

teach how the art taught and practiced methods of nuclear transfer differ from those instantly claimed.

The specification clearly indicates the reliance of the art to practice the instant invention, and thus, the

only working embodiments which are enabled are those specifically supported by the art. Lacking the

necessary guidance, the specification fails to provide a nexus between art-recognized limitations and the

ability to practice the full scope of the invention as presently claimed. In view of the lack of guidance,

working examples, breadth of the claims, the level of skill in the art and the state of the art at the time of

the claimed invention was made, it would have required one of skill in the art undue experimentation to

practice the invention as claimed.

Claim 68 is not enabled for the full breadth of the claim for the reasons set forth above and, as

well, because it fails to recite any methods steps. Without reciting the steps of the method, one would not

know how to carry out the method or if the method carried out is that which is claimed.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

subject matter which the applicant regards as his invention.

Claims 1-28,30-33 and 68-71, 82-84, and 94-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 is unclear in the recitation of a 'rejuvenating a primary cell' because the method as claimed does not result in modifying the cell per se, rather results in a different and unique cell. Similarly, claims 21 and 22 comprise a step of rejuvenating a cell. The method as instantly claimed encompasses nuclear transfer techniques wherein the nucleus of the first cell is transferred into a second recipient cell. Once the genetic material is removed from the first cell it is no longer a cell, nor when it is transferred to the recipient cell is it the same cell, rather it is a chimeric cell. Further, in the formation of a teratoma, it is recognized in the art that the cells often do not maintain the proper ploidy or the properties of terminally differentiated cell. While it is not contested that following the instantly claimed method steps the artisan could obtain a cell which resembles cell type of the initial primary cell, however it is unclear if this represents a rejuvenated form of the initial cell. Further, a common property of many primary cells is terminal differentiation wherein the cell no longer proliferates. For example, in view of claim 2, it is unclear if the rejuvenated primary cell would also be terminally differentiated, and if unable to proliferate, or near senescence, would it still be considered rejuvenated? Though the method steps are straightforward and clear, the metes and bounds of what a rejuvenated primary cell is, and whether practicing the steps results in said rejuvenated cell is unclear. Claims 2-7,17,18 and 69 depend from claim 1. Claims 23 and 24 depend from claim 21. Claim 70 depends from claim 22.

Claims 3,32,33 and 94 are unclear because it is not known what the source of the control teratoma is. Teratomas are not generated by nuclear transfer. It is not clear how the control teratoma is made.

Claim 4 is unclear because it depends from itself. For the sake of compact prosecution it will be interpreted as being dependent on claim 3.

Claims 7,14, 82 and 95 are vague and unclear because the nature of the alteration of the genome is not adequately described. It is unclear if a modification is made to the primary cell, the rejuvenated primary cell and when the modification is introduced. Dependent claims 17-20 are included in this rejection because they fail to clarify the basis of the rejection. Claims 17 and 18 depend from claim 7. Claim 83 depends from claim 82. Claim 96 depends from claim 95.

Claim 8 is confusing because the antecedent basis of the second control teratoma in the final step is unclear. It is unclear if the teratoma is generated by the primary cell, the recipient oocyte or the ICM. Claims 9-16,19 and 20 depend from claim 8.

Claim 13 is unclear in the recitation of "for transplantation into a patient in need of a transplant" because it is unclear if this is an intended use for the tissue or a limitation wherein the tissue generated must be capable of being transplanted.

Claim 25 is confusing and unclear because an animal with the same genotype cannot be genetically different so cannot be altered. From the recited method steps it is unclear how the animal is genetically altered. Claims 26 and 28 depend from claim 25.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claim lacks any active method steps. Claim 71 depends from claim 27

Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claim lacks any active method steps.

Claim 84 is unclear because the metes and bound of the terminology "substantially the same" is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent.

Claims 1-39 and 68-105 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Strelchenko et al. (US Patent 6,011,197) or Damiani et al. (US Patent 6,258,998) as evidenced by Evans et al. (Nature Genetics 23:90-93).

Presently, the claims encompass a method for rejuvenating a cell by the use of nuclear transfer technology. The method as instantly claimed is subject to 35 USC 112, first and second paragraph, rejections. In light of the teachings of the instant specification and the specific steps recited in the instant claims, the method is drawn generally to the use of nuclear transfer methods to generate a primary cell. In view of 35 USC 112, second paragraph, issues regarding the breadth of the claims can be reasonably interpreted to encompass a method of nuclear transfer and isolation of a differentiated cell from a teratoma. In addition, dependent claims are drawn to genetically modifying the rejuvenated cell. Again, in view of the above stated issues under 35 USC 112, second paragraph, the claims can reasonably interpreted to encompass any form of genetic modification.

Strelchenko et al. teach a method of nuclear transfer wherein the resulting cell is used in methods to clone a bovine. Damiani et al. teach a method of nuclear transfer wherein the resulting cell is used in methods to clone an ovine. Further, Strelchenko et al. and Damiani et al. each teach that the methodology can be used to generate an animal in which a heterologous sequence is introduced. In addition, though Strelchenko et al. and Damiani et al. do not specifically teach that they transfer or exchange of heterologous genetic material from the mitochondria, at the time of the claimed invention, it was recognized that in performing nuclear transfer techniques that enucleation and the transfer of nuclei resulted in the exchange of mitochondria as evidenced by Evans et al. The specification relies on the methods taught in the art for the practice of the claimed invention, and since practicing the methods inherently transferred mitochondria, the methods of Strelchenko et al. and Damiani et al. anticipate the claims.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (In re Ludke). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain, and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA i977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). In the instant case, it is unclear how the instantly claimed methods and the resulting cells from said methods are materially different from the methods of nuclear transfer known and taught in the art. Thus, the methods taught in Strelchenko et al. and Damiani et al. each anticipate the instantly claimed methods and cells produced by said method.

Claims 1-39 and 68-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Robl et al. (WO 98/07841) as evidenced by Evans et al. (Nature Genetics 23:90-93, 1999).

The claims are summarized above.

Robl et al. taught a method of cross-species nuclear transfer wherein the resulting cell is a chimeric cell comprising an enucleated oocyte which is different from that of the transferred nuclei. Robl et al. do not specifically teach that they transfer any specific amount of mitochondria, however at the time of the claimed invention it was recognized that in performing nuclear transfer techniques that enucleation and the transfer of nuclei resulted in the exchange of mitochondria as evidenced by Evans et al. The specification relies on the methods taught in the art for the practice of the claimed invention, and since practicing the methods inherently transferred mitochondria, the methods of Robl et al. anticipate the claims as they are drawn to generating a genetically modified cell. As noted above, where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (In re Ludtke). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103. jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products, hi re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531,173 USPQ 685 (1972). In the instant case, it is unclear how the instantly claimed methods and the resulting cells from said methods are materially different from the methods of nuclear transfer known and taught in the art. Thus, the methods taught in Robl et al. anticipate the instantly claimed methods and cells produced by said method.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should

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be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally

be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter

Paras can be reached on (571) 272-4517. The fax phone number for the organization where this

application or proceeding is assigned is 571-273-8300.

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Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR

CANADA) or 571-272-1000.

Valarie Bertoglio

Examiner

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